

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 3-4, 6-17, 20-26, 28-32 and 35-40 and 42 are now pending. Claim 41 is cancelled herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

The Specification has also been amended herein to recite that “Non-invasive vaccination onto the skin (NIVS) can improve vaccination schemes because skin is an immunocompetent tissue and unlike delivery of DNA-based vaccines using a gene gun or a needle, this non-invasive procedure requires no specially trained personnel or equipment.” Support for this amendment can be found in USSN 60/075,113, filed February 11, 1998, to which the present application claims priority and which is incorporated into the present application in its entirety by reference. Accordingly, no new matter is introduced by entry of this amendment.

II. EFFECTIVE PRIORITY DATE

The Office indicates that the present application has been afforded an effective priority date as of the filing of the present application, i.e., January 18, 2002, as the priority documents allegedly do not disclose a method of non-invasive immunization or induction of systemic immune response to a gene product in an animal comprising contacting the skin of said animal with a bacterium. Applicants respectfully disagree.

The Examiner is respectfully invited to review the immediate parent application, USSN 09/563,826, now US Patent No. 6,348,450, at column 2, line 35, of the published patent, wherein it is described that the vector utilized in the methods of non-invasive immunization or induction of a systemic immune response can be "bacterial". Further disclosure of the use of bacterial vectors can also be found in US Patent No. 6,348,450 at column 6, lines 59-65; column 10, lines 15-23; column 15, lines 32-37; and at column 17, lines 55-59, wherein it is stated that "[a]ll forms of genetic vectors including ... bacterial vectors ... when used as skin-targeted non-invasive vaccine carriers, are within the methods contemplated by the invention."

Accordingly, Applicants respectfully submit that the effective filing date of the present application should be at least the May 3, 2000 filing date of the parent application, USSN 09/563,826, now US Patent No. 6,348,450. Applicants respectfully request that the text of US Patent No. 6,348,450 be reviewed in light of the citations provided above, such that effective filing date of the present application is reconsidered and is now deemed to be at least May 3, 2000.

III. THE OBJECTIONS TO THE SPECIFICATION ARE OVERCOME

The Office Action objected to the title of the application as being non-descriptive. It is respectfully submitted that the amendment herein has amended the title, such that this objection is overcome.

The Office Action also objected to the abstract as being too long. It is respectfully submitted that the amendment herein includes a new abstract, which more accurately describes the claimed subject matter, and which is now a total of 112 words, within the 150 word limit set forth in MPEP §608.01.

Accordingly, reconsideration and withdrawal of the objections to the application are respectfully requested.

IV. THE DOUBLE PANTENTING REJECTIONS ARE OVERCOME

Claim 41 was objected to under 37 C.F.R. § 1.75 as allegedly being a substantial duplicate of claim 1. The objection is respectfully traversed. Claim 41 has been cancelled herein without prejudice, rendering the objection moot.

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-42 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-42 of copending Application Serial No. 10/346,021. And, claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-42 of copending Application Serial No. 10/116,963. The rejections are respectfully traversed.

Applicants verily believe that the present application is in condition for allowance as a result of the amendments and remarks herein. Accordingly, as neither USSN 10/116,963 nor 10/346,021 have been found allowable, it is respectfully requested that the provisional double-patenting rejections be withdrawn in favor of a double patenting rejection in each of USSNs 10/116,963 and 10/346,021 over the present application.

V. **THE ART REJECTIONS ARE OVERCOME**

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-42 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Krieg *et al.* (U.S. Patent No. 6,339,068). The rejection is respectfully traversed.

Initially, it is respectfully submitted that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

Applying the law to the instant facts, in order for the rejection under Section 102(e) to be proper, Krieg *et al.* must teach a method of “non-invasive immunization” which comprises “contacting skin of the animal with a bacterial vector.” It is again respectfully submitted that Krieg *et al.* does not teach such non-invasive immunization, contrary to the assertions in the Office Action.

Indeed, when interpreting the scope of the pending claims, including the term “non-invasive”, the claims must be read in light of the specification. Here, the specification, both at page 5, lines 18-20 wherein it is stated that “[c]urrent modes for the administration of genetic vaccines has focused on invasive procedures including needle injections, scarification, and gene gun-mediated penetration” (emphasis added), and at page 8, lines 12-21 as amended herein, wherein the present non-invasive administration is described as being “unlike delivery of DNA-

based vaccines using a gene gun or a needle”, clearly provides that the term non-invasive excludes the use of gene guns.

Furthermore, Applicants also respectfully direct the Examiner’s attention to the examples provided in the application as further examples of administration that would constitute non-invasive techniques. The examples utilize vectors that were “pippetted” onto the skin of the animals, which is akin to the use of an eyedropper or other similar item to apply a liquid to the outermost surface of the skin, without causing the penetration of the skin. These examples are consistent with what one of skill in the art would consider a non-invasive administration comprising contacting the skin or topically applying to the skin the vectors of the present invention. One of skill in the art would not consider the use of a gene gun consistent with non-invasive administration or with topical application.

The Office Action states that “clearly the vectors applied ... all invade the surface of the skin and either infect or are taken up by the cells of the subject” and that as a result, “use of a gene gun is considered a non-invasive means of delivery and is encompassed by the claims.” Office Action at 8. The Office Action clearly overlooks the distinction between the administration of vectors onto intact skin wherein the cells themselves are responsible for uptake of the vectors and administration via a gene gun where the vectors forcibly penetrate the skin during the administration.

This distinction is evidenced by the language in Krieg *et al.* that states “[p]lasmid DNA may be coated onto gold particles and introduced biolistically with a ‘gene-gun’ into the epidermis if [sic] the skin or the oral or vaginal mucosae”. Column 10, lines 54-57. Accordingly, as is explicitly stated in Krieg *et al.*, the use of a gene gun does not deliver the gene products onto the skin as is required by the present claims, but rather the gene gun deliver the gene products into the epidermis.

Accordingly, the use of a gene gun is outside the scope of the present claims as the use of a gene gun is contrary to the claimed “non-invasive” immunization. Therefore, as Krieg *et al.* only teaches the use of a gene gun, and does not teach or suggest the non-invasive application of bacterial vectors to the skin, the rejection is improper and cannot stand. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

REQUEST FOR INTERVIEW

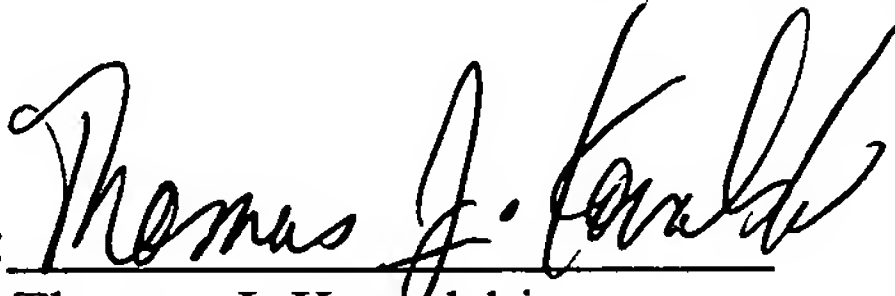
If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

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